

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON**

<b>IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b>	<b>Master File No. 2:12-MD-02327 MDL 2327</b>  <b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>  <b>WAVE 13</b>
<b>THIS DOCUMENT RELATES TO:</b>  <i>Donna Parks v. Ethicon, Inc. and Johnson &amp; Johnson</i> <b>Case No. 2:14-cv-10221</b>	

**DEFENDANTS' REPLY TO PLAINTIFF'S OPPOSITION TO DEFENDANTS'  
MOTION FOR SUMMARY JUDGMENT**

Defendants' Motion for Summary Judgment established that there was no genuine issue of material fact on all of Plaintiff's claims. Plaintiff's failure to warn and other fraud-based claims fail for lack of causation. Plaintiff's negligence-based warnings claims fail for the same reason as their strict-liability variant, and her negligent design defect claim fails for lack of expert testimony connecting Plaintiff's injuries to a specific defect in the device. Plaintiff's consumer protection act claims fail because Plaintiff has not given pre-suit notice and/or cannot establish an economic loss. The breach of warranty claims fail because they are barred by the statute of limitation, for which the discovery rule does not apply under California law.

In her Response, Plaintiff concedes her claims for Strict Liability – Manufacturing Defect (Count II), Strict Liability – Defective Product (Count IV), Strict Liability – Design Defect (Count V), and Loss of Consortium (Count XVI). *See* Pl.'s Opp'n to Defs.' Motion for Summ. J. ("Pl's Resp."), Doc. 44, at 2, n.1, 18. Defendants are entitled to summary judgment on these claims.

## ARGUMENT

### **I. The failure to warn (Count III) and other fraud-based warning claims (Counts VI, VII, VIII, IX, XI, XIII) should be dismissed for lack of causation.**

Plaintiff cannot meet her burden of proof to show that the Gynemesh PS warnings were a legal cause of her injuries. In her Response, Plaintiff claims that Dr. Menefee testified only that he was aware of general complications related to “pelvic floor surgeries” and to “mesh” in general, and this is insufficient to show that he was aware of “all the serious complications associated with the transvaginal use of Gynemesh PS in January 2010.” Pl.’s Resp. at 6. This argument ignores the fact that it is Plaintiff’s burden to show that Dr. Menefee was not aware of the risks of Gynemesh PS.

Plaintiff’s real contention is that Defendants failed to warn of the “frequency, duration, and severity” of the disclosed risks. Pl.’s Resp. at 6. Plaintiff has not pointed to (and Defendants are not aware of) any cases holding that California law requires a manufacturer to provide duration, severity, or frequency rates concerning a particular adverse event, and courts from other jurisdictions that have considered this supposed duty have largely rejected it. *E.g.*, *McDowell v. Eli Lilly & Co.*, 58 F. Supp. 3d 391, 405 (S.D.N.Y. 2014) (New York law); *Ames v. Apothecan, Inc.*, 431 F. Supp. 2d 566, 573 (D. Md. 2006) (Maryland law); *Percival v. Am. Cyanamid Co.*, 689 F. Supp. 1060, 1063-64 (W.D. Okla. 1987) (Oklahoma law); *Hurley v. Lederle Labs.*, 651 F. Supp. 993, 1002-03 (E.D. Tex. 1986) (Texas law), *rev’d on other grounds*, 863 F.2d 1173 (5th Cir. 1989); *Smith v. Wyeth Labs.*, No. Civ.A. 84–2002, 1986 WL 720792, at \*9–10 (S.D. W. Va. Aug. 21, 1986) (West Virginia law); *Calabrese v. Trenton State College*, 392 A.2d 600, 604-05 (N.J. Super. App. Div. 1978) (New Jersey law) (rabies vaccine manufacturer had no duty to provide “available statistical data on the remoteness of the danger of rabies”).

Plaintiff also argues that summary judgment should be denied because Dr. Menefee testified that it was his practice to read product IFUs and testified that he believes it is important that products have package inserts. From this testimony, Plaintiff argues that the alleged insufficient warnings in the Gynemesh PS IFU were “important to [Dr. Menefee’s] risk benefit process” and summary judgment should be denied. Pl.’s Resp. at 10. But Plaintiff wholly ignores Dr. Menefee’s testimony that Dr. Menefee stated clearly that he does not *rely* on IFUs, including the Gynemesh PS IFUs, in making his surgical decisions. *See* Ex. 4 to Defs.’ Mot. for Summ. J. at 140:4-7; 148:23-149:1. Because Plaintiff’s argument is contradicted by the implanting physician’s testimony, it should be rejected.

Plaintiff has no competent summary judgment evidence demonstrating that Dr. Menefee was unaware of the risks of Gynemesh PS or that he relied on the IFUs included with that product. Under well-settled law, this is fatal to Plaintiff’s failure to warn-based claims, and summary judgment should be entered.

## **II. Plaintiff’s negligence-based claims (Count I, Count IX) fail as a matter of California law.**

In its motion, Ethicon argued that Plaintiff’s negligence-based warnings claims relied on the same series of facts as her strict liability counterparts and failed for the same reason—lack of causation. *Valentine v. Baxter Healthcare Corp.*, 81 Cal. Rptr. 2d 252 (Cal. App. 1999) (“the directed verdict on negligent failure to warn was correct because the strict liability verdict in *Valentine I* foreclosed a finding of negligent failure to warn”). Plaintiff’s response arguments concerning Dr. Menefee’s testimony fare no better here and summary judgment in Ethicon’s favor is appropriate.

Ethicon also argued that Plaintiff’s negligence-based design defect claim—which does not have a strict liability variant—fails for lack of causation because Plaintiff’s specific-

causation expert, Dr. Daniel Elliott, failed to establish that one of the purported defects in the device caused Plaintiff's alleged injuries. Instead, he simply opined that "the Ethicon" caused the injuries.

In response, Plaintiff claims that Dr. Elliott opined in his report that the chronic inflammatory reaction associated with Plaintiff's mesh caused scarring and narrowing of her vagina. Pl.'s Resp. at 12 (citing page 62 of Dr. Elliott's report). Presumably, Plaintiff refers to a single conclusory sentence on page 62 of Dr. Elliott's report: "As a result of the implantation of Ethicon [sic] and the subsequent reaction, Ms. Parks' vagina has scarred and narrowed resulting in severe pain." This is insufficient to establish causation because it identifies no defect in the device that allegedly caused Plaintiff's injuries. Summary judgment should be granted.

### **III. Plaintiff cannot establish a consumer protection claim (Count XIII).**

In its Motion, Ethicon established that Plaintiff cannot establish a consumer protection act claim under either the Consumer Legal Remedies Act ("CLRA") or California's Unfair Competition Law ("UCL"). First, any CLRA claim is barred by Plaintiff's failure to give written notice of the defect and an opportunity to cure it 30 days or more before filing suit. Cal. Civ. Code § 1782(a) (stating that "thirty days or more" before filing a CLRA action "for damages," a consumer shall notify the potential defendant of alleged violations and demand repairs or corrections). Failure to give notice before filing a complaint for damages is fatal to a claim under the CLRA. *Davis v. Chase Bank U.S.A., N.A.*, 650 F. Supp. 2d 1073, 1088-89 (C.D. Cal. 2009). In response, Plaintiff makes the convoluted argument that "[u]nder Section 1780 of the CLRA, any consumer who suffers damage can obtain actual damages, restitution of property, or injunctive relief," that she has suffered "some sort of damage," and that "[i]f notice is provided, within 30 days Subsection 1781(d) makes clear the Complaint can be amended to assert a claim for damages "without leave of court." Pl.'s Resp. at 13. She claims that she "need not comply

with the notice requirement to assert a claim for relief other than damages,” that she does seek relief other than damages, and that she can simply amend her Complaint “without leave of Court after the 30-day period runs” after “send[ing] the CLRA demand letter,” and *then* “proceed with a damages claim.” *Id.* Due to this series of hypotheticals, she asserts that “summary judgment cannot be granted on this claim,” citing *Morgan v. AT&T Wireless Services, Inc.*, 177 Cal. App. 4th 1235, 1260-61 (2009) in support. *Id.* But Plaintiff has *not* amended her complaint. Unlike this case, the *Morgan* plaintiffs provided notice before amending their complaint to seek damages under the CLRA. Thus, as noted by one court:

*Morgan* is easily distinguishable from the present matter. Although the plaintiffs in that case provided notice to the defendant after the original complaint was filed, that notice was provided more than thirty days before the third amended complaint was filed, which became the operative complaint in that case. Unlike the plaintiffs in *Morgan*, Beck has only filed one complaint, which still remains operative. Thus, his notice to FCA continues to be post-filing of the complaint.

*Beck v. FCA US LLC*, 273 F. Supp. 3d 735, 748 (E.D. Mich. 2017) (applying California law) (emphasis in original).

Plaintiff also cannot pursue a claim under California’s Unfair Competition Law. According to Plaintiff, Defendants have not “establish[ed] that Plaintiff has not suffered some form of economic loss.” Pl.’s Resp. at 15. Plainly, it is Plaintiff’s burden on summary judgment to demonstrate that she “(1) has suffered injury in fact, and (2) has lost money or property as a result of such unfair competition” in order to establish standing under the UCL. *Pom Wonderful LLC v. Welch Foods, Inc.*, No. CV-09-567-AHM(AGR<sub>x</sub>), 2009 WL 5184422, at \*2 (C.D. Cal. Dec. 21, 2009) (internal quotation marks omitted). Plaintiff has failed to set forth any evidence demonstrating her “economic loss” and summary judgment should be granted.

**IV. The breach of warranty claims (Counts XI and XII) are barred by the statute of limitations.**

California's UCC provision imposes a four-year statute of limitations, which accrues "when tender of delivery is made." Cal. Com. Code § 2725(1), (2). No discovery rule applies. *See id.* § 2725(2) ("A cause of action accrues when the breach occurs, regardless of the aggrieved party's lack of knowledge of the breach".) Here, tender of delivery occurred on January 8, 2010, at the latest, and the four-year statute of limitations expired on January 9, 2014. Plaintiff did not file this lawsuit until February 13, 2014. Accordingly, Plaintiff's warranty claims are time-barred.

Plaintiff erroneously quotes California Commercial Code § 2725(4), stating that "a plaintiff's claim for express and implied warranty accrues 'when he discovers or should have discovered the breach.'" Pl.'s Resp. at 15 (quoting Cal. Comm. Code § 2725(4)). California Commercial Code § 2725(4) actually states that "This section does not alter the law on tolling of the statute of limitations nor does it apply to causes of action which have accrued before this code becomes effective."<sup>1</sup> Plaintiff, however, points to no provision of California law that would toll this statute of limitations.

California Commercial Code § 2725(2) states that

A cause of action accrues when the breach occurs, regardless of the aggrieved party's lack of knowledge of the breach. A breach of warranty occurs when tender of delivery is made, except that where a warranty explicitly extends to future performance of the goods and discovery of the breach must await the time of such performance the cause of action accrues when the breach is or should have been discovered.

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<sup>1</sup> California Commercial Code § 2725 became effective in 1967.

Here, the warranty does not explicitly extend to future performance of the product; therefore, there is no discovery rule applicable. *See, e.g., Lucas v. Breg, Inc.*, 212 F. Supp. 3d 950 (S.D. Cal. 2016) (Delayed discovery rule under future performance exception to four-year statute of limitations for breach of warranty claims under California law was not applicable in consumers' putative class action alleging that manufacturer misrepresented risks of bodily injury associated with continuous use of its cold therapy device, and, thus, claims accrued when tender of delivery was made.).

Plaintiff's reliance on *Mills v. Forestex Co.*, 108 Cal. App. 4th 625, 642 (2003), is not applicable to this case. In *Mills*, the lumber manufacturer of siding used in the construction of the plaintiff's garage involved a 25-year warranty on the siding; thus, the cause of action for breach of warranty of future performance, *i.e.*, the 25-year warranty on the siding, accrued upon discovery of the breach. Likewise, Plaintiff's reliance on *Yi v. BMW of N. Am.*, 2018 WL 3359016, \*17-18 (C.D. Cal. May 24, 2018) is not applicable to this case because it also involved extended express warranties on the plaintiff's BMW vehicle. Again, the warranty in this case does not explicitly extend to future performance of the product; therefore, there is no discovery rule.

Here, the four-year statute of limitations accrued at tender of delivery on January 8, 2010 at the latest, and the four-year statute of limitations expired on January 9, 2014. Plaintiff's warranty claims are time-barred and should be dismissed.

## CONCLUSION

For these reasons, and all of the reasons set forth in Motion for Summary Judgment and Memorandum in Support, summary judgment should be granted, and all of Plaintiff's claims should be dismissed with prejudice.

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I certify that on this day, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ William M. Gage